EXHIBIT 4

LMA™
Better by Design

A Comparative Anatomical Study of Laryngeal Masks

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Department of Anesthesiology, The University of Texas, M. D. Anderson Cancer Center, Houston, Texas, United States.

Edited summary prepared by The Laryngeal Mask Company Limited. May 2005

Introduction and methodology

The clinical and commercial success of the LMA™ laryngeal mask airway has inspired a proliferation of rival devices. The 1996 FDA reclassification of laryngeal masks as Class I devices means that manufacturers no longer have to submit clinical safety and efficacy data to the FDA when registering new masks.

There is, therefore no longer a need to obtain clearance from the FDA to market a laryngeal mask device.

A research team from the University of Texas spent two years studying the behavior of laryngeal mask airways – during insertion, inflation and clinical use. Working on fresh cadavers where the soft tissues are comparable to those of live patients, the team used fluoroscopy to watch the masks being inserted and computerized tomography and fiberoptics to examine their positioning and performance.

Here are the findings.

Methodology

After being granted permission from the institutional review board, fresh human cadavers were used to study the effects of insertion of the supraglottic airways on airway structures. All insertions were performed by an anesthesiologist, who followed the manufacturer's guidelines for size selection and insertion technique for each device. Continuous lateral neck fluoroscopy was performed during each insertion. Fluoroscopic images were reviewed by a board certified radiologist.

Helical computed topography (CT) scans of the cadavers were performed with each supraglottic airway *in situ*. Three-dimensional (3-D) reconstructions of these CT scans were obtained to evaluate the positions of the devices in relation to the airway structures.

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This research was presented as a poster at the American Society of Anesthesiologists Annual Meeting in 2004, and together with additional research form an analysis of 7 Supralaryngeal Airways. This independent research was conducted with sole funding from M.D. Anderson Cancer Center.

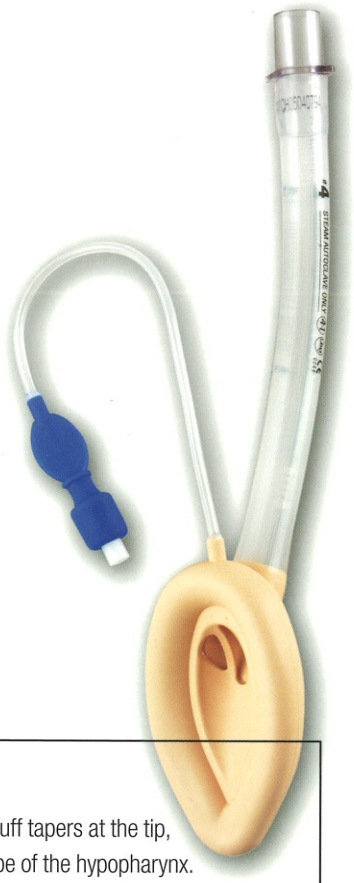
This has been edited to form a summary of the original LMA Classic™ and the two devices closest in concept; the Portex Soft Seal™ and Ambu™ Laryngeal Mask.

Dr David Ferson, who led the research, is a participant of the American Society of Testing and Materials Committee F29 on supralaryngeal airways.

Comparing the masks

When, in the early 1980s Dr Archie Brain began work on the first LMA™ airway design he was guided by the principle of anatomical accuracy. He took multiple plaster casts of the human pharynx, created latex models from these casts and, with Ethical Committee approval, experimented both with self-insertion and on more than 7,000 patients in the prototype phase. The result was a mask that accurately mapped the anatomy of the pharynx.

Portex Soft Seal™ and Ambu™ Laryngeal Mask airways lack the same level of anatomical accuracy. Side-by-side, the differences are obvious even to the untrained eye.

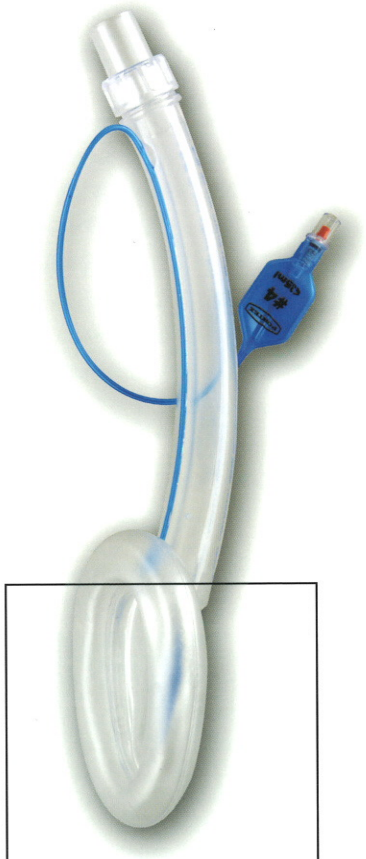


LMA™ airway

The distinctive shape of the cuff tapers at the tip, following the anatomical shape of the hypopharynx. The back plate, deep at the rear, becomes shallower at the front. There are aperture bars.

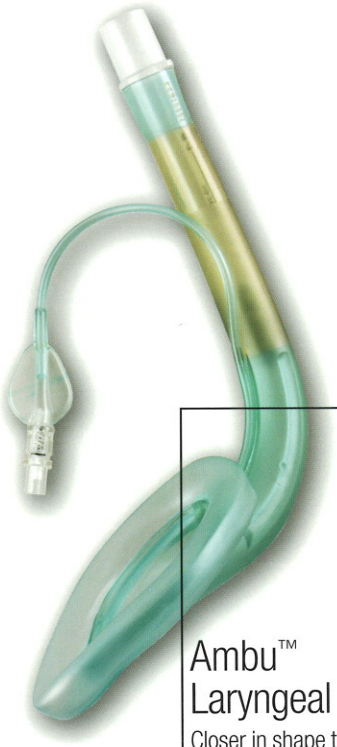
Inserting the masks

Ferson *et al* used fluoroscopy to study the behavior of the masks during insertion. The Portex Soft Seal™, which lacks the tapered leading edge of the LMA™ airway, and the back plate, was the most problematic to insert. The Ambu™ Laryngeal Mask's rigid, pre-curved airway, makes insertion easy.



Portex Soft Seal™

The cuff does not taper at the tip: it is a perfect oval. A larger diameter airway tube. No back plate. No aperture bars. Inflation line attached to airway tube.

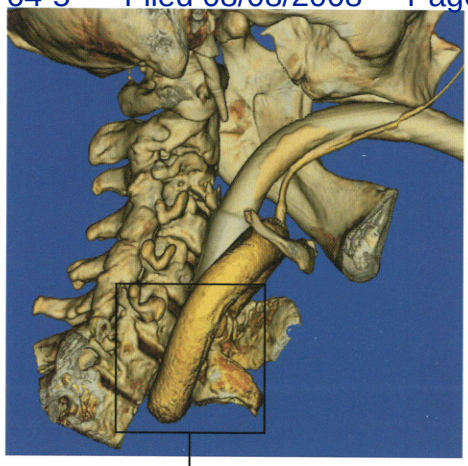


Ambu™ Laryngeal Mask

Closer in shape to the LMA™ airway, but not identical. A larger and more rigid pre-curved airway tube. No back plate. No aperture bars. Inflation line attached to airway tube.

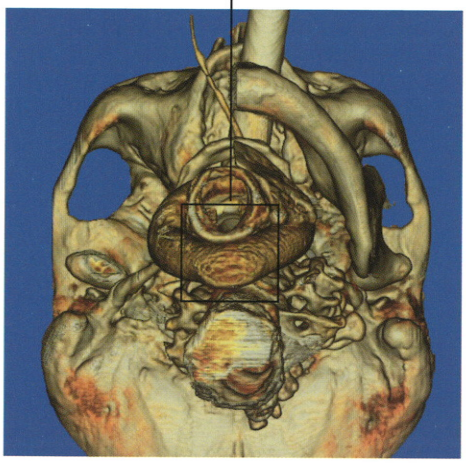
Positioning: key differences

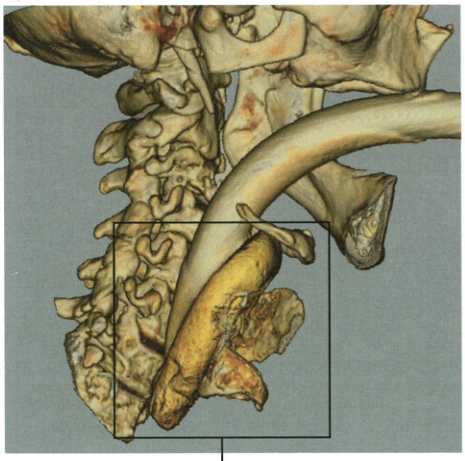
Ferson *et al* used computerized tomography and fiberoptics to examine the positioning of the three masks. These CT scan images show the masks in place within the same cadaver. Soft tissues and other inessentials have been removed from the images, giving a clear picture of how the masks behave *in situ* and how the differences in design may affect performance.



LMA™ airway

Here, the LMA™ airway sits on the upper esophageal sphincter. The cuff, shaped anatomically, retains its shape, forming a good seal.

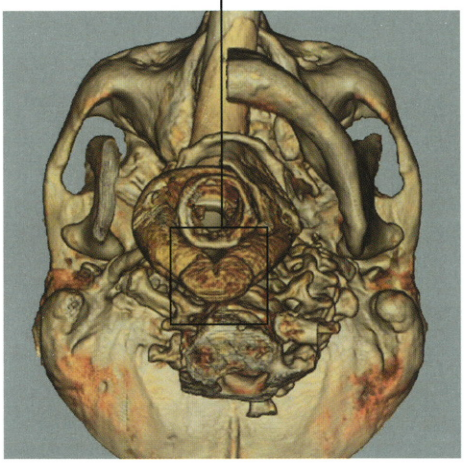


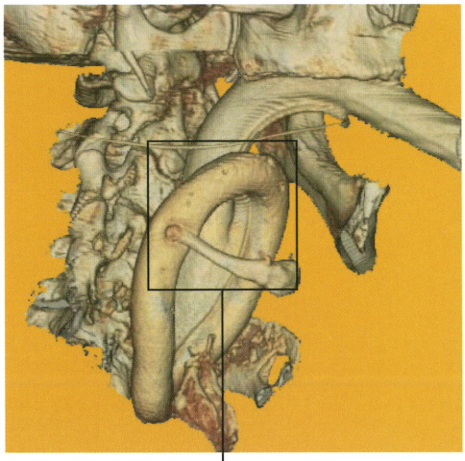


Portex Soft Seal™

The tube of the Portex Soft Seal™ extends all the way to the tip of the cuff, resulting in placement below the hyoid bone, making the mask more invasive. Using fluoroscopy, the soft tip was noted to bend backwards on insertion.

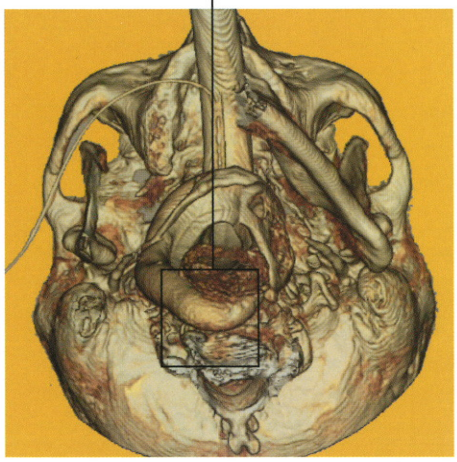
Without precise anatomical shape, the cuff of the Portex Soft Seal™ is itself shaped by the pressure of surrounding tissue. At the tip the cricopharyngeal muscle causes herniation of the cuff, creating a small gap.





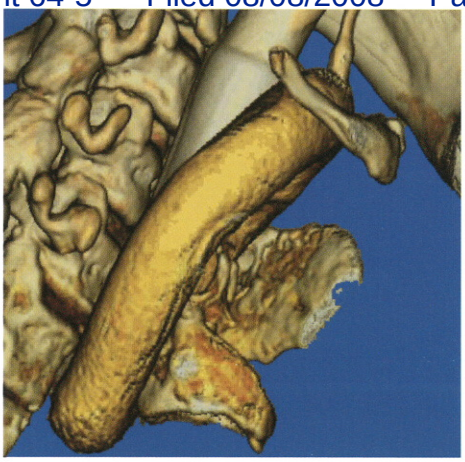
Ambu™ Laryngeal Mask

While the size and pre-curved shape of Ambu™ Laryngeal Mask's airway tube makes it easy to insert, it also causes the mask to sit much higher than the other two masks, here pressing on the hyoid bone. Because it sits higher, the Ambu™ Laryngeal Mask's tip is not in contact with the upper esophageal sphincter.



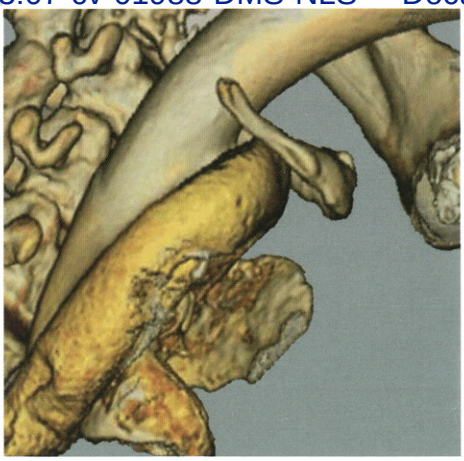
Clinical implications and risks

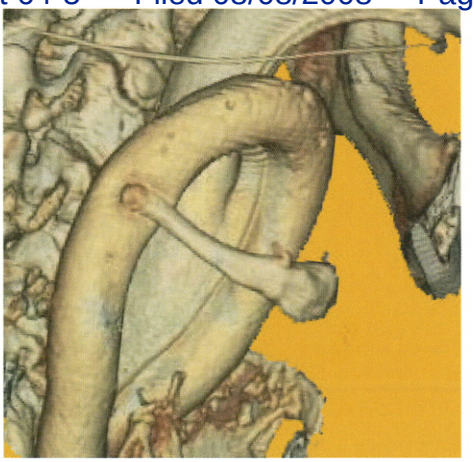
So far the research has demonstrated clear differences in the design of three masks and in their positioning. But what are some of the potential clinical implications?

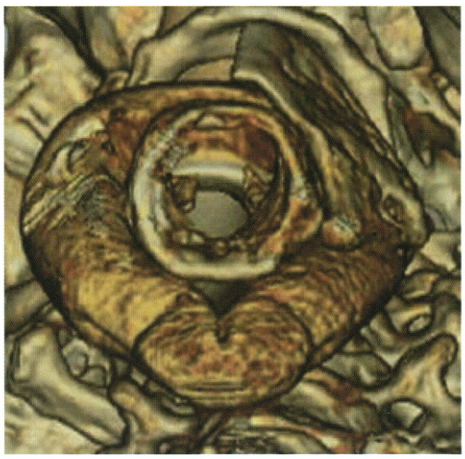


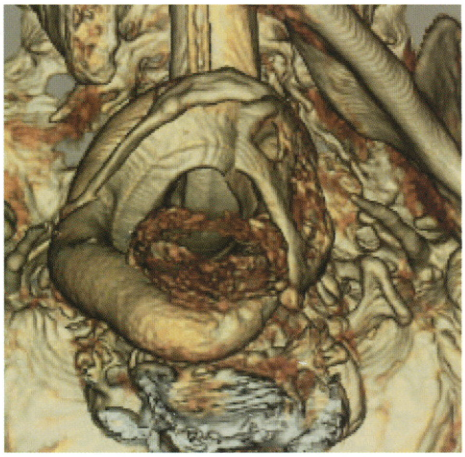
LMA™ airway

No clinical implications with proper sizing, insertion and inflation volumes.









Portex Soft Seal™

As well as being potentially more invasive and more difficult to insert, the cuff of the Portex Soft Seal™, as we have seen in this case, herniates. That makes it more prone to imperfect sealing. The channel that is created in this instance between the esophagus and the trachea increases the risk of gastric insufflation, regurgitation and aspiration.

Ambu™ Laryngeal Mask

The Ambu™ Laryngeal Mask's high position is dictated by the pre-curved shape and the rigidity of its tube. This design helps insertion but may cause the cuff to press against the hyoid bone in some cases. There is a danger that the hypoglossal nerve, which governs motor functions of the tongue can be caught between the mask and the hyoid bone, leading to nerve palsy and problems with speech and swallowing. The failure to cover the esophagus also increases the risk of gastric insufflation, regurgitation and aspiration.

Comparisons and conclusion

	LMA™ airway	Portex Soft Seal™	Ambu™ Laryngeal Mask
Main differences	Anatomical shape of cuff and back plate. Aperture bars.	Oval cuff. No back plate. No aperture bars.	Pre-curved, rigid airway tube. No back plate. No aperture bars.
Insertion	Easy insertion, minimal risk of trauma.	Risk of problematic insertion.	Easy insertion, minimal risk of trauma.
Positioning	Cuff retains shape. Sits on the esophagus.	More invasive. Cuff can herniate.	Sits high, potentially pressing on hyoid bone. Possible lack of contact with esophagus.
Clinical implications	None, provided proper sizing, insertion and inflation volume.	Prone to imperfect sealing. Greater risk of gastric insufflation, regurgitation and aspiration.	Hypoglossal nerve may be caught between mask and hyoid bone. Greater risk of gastric insufflation, regurgitation and aspiration.

Better by Design™

Turn over to see how the design differences of the LMA™ airway help minimize risk and deliver better clinical outcomes.

LMA™ AIRWAYS

200 million successful uses worldwide

17 years of experience

Proven clinical performance

Familiar product

ASA difficult airway algorithm

AHA 2000 Resuscitation Guidelines

More than 2,500 clinical references

Designed by an anesthesiologist

Familiar patient sizing guidelines and inflation volumes

Familiar insertion technique

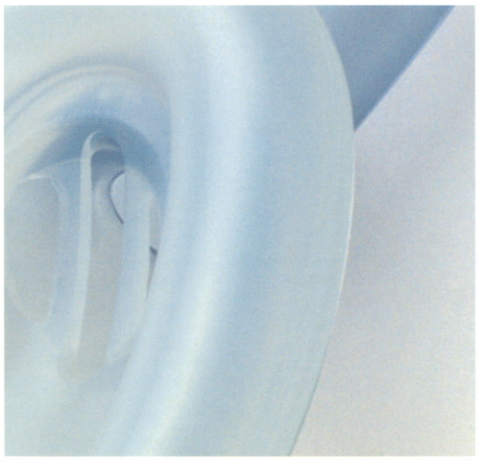
Similar cuff design with all LMA™ products

System of products

LMA™ airway educational support

Proven quality

Superior service history



Component	Design feature	LMA™ benefit with design feature	Other designs and issues
Airway tube	Diameter	Tube diameter designed to reduce stimulation to the patient	Larger airway tubes may stimulate patient by pushing jaw open more; may result in patient biting down on airway tube if anesthesia becomes light
	Ability to pass ETT	Standard 15 mm connector limits the size of larger ETTs for tracheal intubation	Despite larger airway tube, standard 15 mm connector limits the size of larger ETTs for tracheal intubation
	Pliability	The pliability of the tube is designed to facilitate insertion and minimize mucosal pressure when inserted, and while in position	A pre-curved or stiffer tube may not allow mask to insert smoothly or sit properly
	Resistance to kinking	Tube designed to be flexed up to 180° without kinking	An improperly designed tube may collapse on itself and be obstructed or restricted at 180°
	Aperture bars	Aperture bars are designed to keep the epiglottis from obstructing the airway Aperture bars also serve as convenient points of orientation during fiberoptic use	With no aperture bars, epiglottis can enter the ventilatory path, possibly causing airway obstruction Lack of aperture bars makes it more difficult to orient during fiberoptic use
Cuff	Taper	Tapered tip designed to plug the upper esophageal sphincter while creating a low pressure seal reducing the likelihood of gastric insufflation	A more rounded tip may not sufficiently plug the esophageal sphincter and may allow insufflation of the stomach
	Profile	Wedge shape is designed for anatomical fit in the hypopharynx and ease of placement	A rounded shape may be harder to place and may not fit the anatomy optimally
	Material characteristics	When properly deflated, the cuff is designed to resist folding over of the tip, improving ease of insertion and placement	A thinner cuff material may allow the tip to fold over more easily during insertion resulting in more difficult insertion and placement
	Seal location	Low pressure seal around glottic opening	Higher profile masks or oropharyngeal cuffs increase seal pressure at the base of the tongue. This may not allow for leaks around the distal cuff to exit the oropharynx, possibly increasing the risk of stomach insufflation
	Back plate	Provides strength to the bowl of the mask to resist medialization and downfolding	Lack of back plate reduces support for the cuff and may lead to unwanted folding of the cuff and potential airway obstruction
	Back plate	Enables thin leading edge when cuff is deflated facilitating insertion and reducing trauma	Lack of back plate results in more prominent and stiffer leading edge causing more difficult insertion and possibly cause more trauma
	Inflation line	Inflation line separate from the airway tube to reduce chance that inflation line may be bitten through	An inflation line attached to the airway may be bitten through resulting in immediate deflation of mask

LMA-500 04/05

This important study has established that these three laryngeal mask airways are not the same. Instead they are designed differently, behave differently and – most importantly – their use carries very different clinical implications.

Choosing a laryngeal mask airway is not just about cost or what you are used to. There is a clinical consideration and a risk assessment that needs to be made too.

Find out more

We hope you have found this edited summary of independent research informative.

To find out more about LMA™ airways
— International call **+44 (0) 1628 852 400** or **www.LMACO.com**
— United States call **(800) 788-7999** or **www.LMANA.com**

The information given in this document is correct at the time of going to press. The manufacturer reserves the right to improve or modify the products without prior notification.

Consult the instructions on indications, contraindications, warnings and precautions, or information on which LMA™ airways are best suited for different clinical applications.

Issue Number: P071E/1,0505
LMA-501 04/05

EXHIBIT 5

From: 202 429 4564 Page: 1/1 Date: 11/15/2004 12:24:59 PM

LEVY & GRANDINETTI
1725 K STREET N.W, SUITE 408
WASHINGTON, D.C. 20006-1423

TELEPHONE: (202) 429-4560
FACSIMILE: (202) 429-4564
E-MAIL: mail@levygrandinetti.com

November 15, 2004

VIA FACSIMILE AND AIR MAIL

Mr. Steve C. Mendell
President, Chief Executive Officer
LMA INTERNATIONAL N.V. and
LMA NORTH AMERICA, INC.
9360 Towne Centre Drive, Suite 200
San Diego, California 92121-3030

Re: Ambu® Laryngeal Mask

Dear Mr. Mendell:

Ambu Inc. manufactures and supplies quality medical devices worldwide. Ambu places patient safety and care at the forefront of every aspect of its business. Ambu's internationally recognized reputation for safe and effective products is its most valuable asset.

A representative of LMA recently informed personnel at a hospital, which is a long-standing customer of Ambu, that the Ambu® Laryngeal Mask "causes nerve damage." Additionally, LMA is distributing literature that bears the equivocating, ambiguous language that Ambu's product "possibly" increases the "chance" of hypoglossal or lingual nerve damage.

Ambu is unaware of any instance of such nerve damage or any peer-reviewed article that suggests that the Ambu® Laryngeal Mask has ever caused hypoglossal or lingual nerve damage. Ambu, as a diligent and responsible corporation, demands any evidence that LMA may have that the Ambu product has caused such nerve damage.

In the absence of such evidence, Ambu demands that LMA immediately cease and desist from rendering any comments or distributing any materials associating the Ambu® Laryngeal Mask with hypoglossal or lingual nerve damage. Ambu views any such suggestion or innuendo associating nerve damage with its product as damaging to Ambu's reputation and business.

Please immediately acknowledge by return facsimile that LMA will comply with the demands in this letter. A lack of response to these demands will be deemed an inability of LMA to substantiate its claims and a refusal to cease its improper activities.

Sincerely yours,

Paul Grandinetti

PG:ceg

cc: Ambu Inc.

EXHIBIT 6

SHEARMAN & STERLING LLP

FAX: 202-508-8100
www.shearman.com

801 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, D.C. 20004-2604
202 508-8000

WRITER'S DIRECT NUMBER:

202.508.8174

WRITER'S EMAIL ADDRESS:
smarzen@shearman.com

November 19, 2004

By Federal Express

Paul Grandinetti, Esq.
LEVY & GRANDINETTI
1725 K Street, N.W., Suite 408
Washington, DC 20006-1423

Re: Ambu® Supraglottic Airway

Dear Mr. Grandinetti:

I represent LMA Virginia, Inc. and LMA North America, Inc. (collectively, "LMA"). Steve Mendell, the Chief Executive Officer of LMA North America, Inc., gave me a copy of your letter on behalf of Ambu Inc. ("Ambu") dated November 15, 2004.

As Ambu should be aware, helical computed tomography scans of cadavers shown at this year's ASA Annual Meeting indicate that the cuff of the Ambu® supraglottic airway can press the Hyoid bone in the same area as the hypoglossal nerve. That pressure could lead to nerve damage. Although the findings from the cadaver study were presented only three weeks ago, and thus have not been published in a peer-reviewed article, a company that claims to "place[] patient safety and care at the forefront of every aspect of its business" – as you claim Ambu does – should be concerned about risks long before they became the subject of "peer-reviewed article[s]" or have actually "caused such nerve damage." Letter from Paul Grandinetti to Steve Mendell (Nov. 15, 2004).

LMA has a justifiable reason for concern about the Ambu® supraglottic airway because Ambu has chosen to promote its device as an LMA® and trade on the reputation of its inventor, Dr. Archie Brain. After 200 million safe uses, more than 2,500 clinical references, and 15 years of experience, anesthesiologists understandably associate the LMA® with the LMA Corporation and Dr. Brain. It has come to the attention of LMA, however, that Ambu is falsely representing

that its supraglottic airway device is a genuine LMA® and was developed in collaboration with Dr. Brain. Three examples suggest the magnitude of the misrepresentations. *First*, an East Coast hospital recently reported that Ambu's sales representative lied that Ambu had spent millions of dollars to have Dr. Brain consult on the development of the Ambu® supraglottic airway and that Dr. Brain agreed that omitting aperture bars benefited the patient. *Second*, at a workshop in the South, Ambu's sales representative falsely told doctors that the Ambu® supraglottic airway is a "disposable Fastrach LMA." *Third*, LMA recently received a written complaint about the Ambu® supraglottic airway, which the user mistakenly believed was a genuine LMA®.

By associating the Ambu® supraglottic airway device with the LMA®, Ambu is trading on the LMA®'s reputation of successful patient outcomes and clinical proof. The confusion caused by Ambu's marketing practices is damaging LMA's reputation and goodwill.

If Ambu intends to live by the values and reputation it claims, it must stop marketing its supraglottic airway device as an LMA® and as a device developed in collaboration with Dr. Brain. It must affirmatively inform anesthesiologists and prospective purchasers that Ambu and its airway device are not related to LMA®, were not developed by Dr. Brain, and are not endorsed by him. And it must respect LMA's intellectual property, including its patents and trademarks.

We look forward to hearing from you or Ambu. In the meantime, LMA reserves its rights under applicable law.

Sincerely yours,

Stephen Marzen

Stephen Marzen

cc: Steve Mendell

#326983

EXHIBIT 7

LEVY & GRANDINETTI
1725 K STREET N.W., SUITE 408
WASHINGTON, D.C. 20006-1419

TELEPHONE (202) 429-4560
FACSIMILE (202) 429-4564
E-MAIL: mail@levygrandinetti.com

December 22, 2004

VIA FACSIMILE AND FIRST CLASS MAIL

CONFIDENTIAL

Mr. Stephen Marzen
SHEARMAN & STERLING LLP
801 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2604

Re: Ambu® Laryngeal Mask

Dear Mr. Marzen:

Ambu investigated the statements made in your correspondence of November 19, 2004, regarding laryngeal masks.

Ambu examined all of the abstracts from the ASA Annual Meeting 2004 and found only one, which discussed the risk of hypoglossal nerve injury and supraglottic airways (Abstract A-1531). The study presented cross-section views, that were obtained from MRI scans, in order to compare a laryngeal mask from your client, LMA, with a SLIPA airway from Hudson-RCI. The study concluded that cuff inflation of the LMA device causes tissue displacement of the tip of the hyoid bone, which is suggestive of increased pressure, whereas possible localized reduction of pressure at this site using a cuffless anatomically pre-shaped sealer may lower the risk of hypoglossal nerve injury.

No abstracts from the meeting include similar observations for the Ambu® Laryngeal Mask. Based on the review of these abstracts, the speculative statements expressed in your letter, concerning risks supposedly related to the Ambu® Laryngeal Mask, are unfounded. Further, by disseminating such erroneous, speculative information, including the marketing materials identified in our previous letter, LMA risks tarnishing its own product's reputation by creating unfounded anxiety over the use of laryngeal masks.

Ambu only promotes the Ambu® Laryngeal Mask as a quality product, which was developed and manufactured by Ambu. Ambu is not promoting its product, as you allege, with your client's "LMA" mark or by suggesting that Dr. Archie Brain collaborated in the development of the Ambu® Laryngeal Mask. Ambu has warned its sales staff against making any such statements and will not tolerate any such statements.

Ambu maintains that fair competition is in the best interest of both of our clients as well as the medical care industry. Ambu expects LMA to honor Ambu's demand that LMA cease alleging that the Ambu® Laryngeal Mask "causes nerve damage" and cease distributing literature stating that Ambu's product "possibly" increases the "chance" of hypoglossal or lingual nerve damage or any similar unsubstantiated allegations.

Ambu expects the management of LMA to behave responsibly and considers this matter closed. If you or your client have any questions, please do not hesitate to contact this firm.

Sincerely yours,

Paul Grandinetti

PG:elb

cc: Mr. F. Homa
Mr. O. Køhnke